

The Applicants submit that the amendment to the specification and the submittal of the hereinabove noted Monograph overcomes the Examiner's objection to the specification under 35 U.S.C. 112, first paragraph.

In addition, claims 22 and 23 have been amended to incorporate the element polysorbate 80 and to correct for the misspelling of "glycerine".

The Applicants submit that this amendment to the claims overcomes the Examiner's rejection of claims 22 and 23 under 35 U.S.C. 112, first paragraph.

Further, claims 1-4, 9, 22-24 have been rejected by the Examiner under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention.

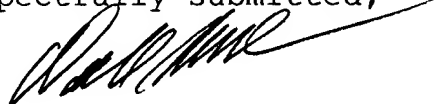
In response thereto, the Applicants have now amended the specification to define the term "Pemulen" and have submitted prior art publications showing that the trademark "Pemulen" has the definition inserted into the specification.

AMENDMENT (2003)

Page 4

In view of the fact that claims 5-8 have been canceled by the present amendment and the Examiner's indication that claims 1-4, 9 and 22-24 would be allowable if rewritten or amended to overcome the rejection under 35 U.S.C. 112, the Applicants submit that the application is now in condition for allowance and such action is respectfully requested.

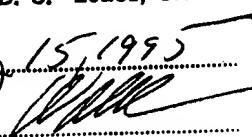
Respectfully submitted,



Walter A. Hackler
Reg. No. 27,792
Attorney of Record
2372 S.E. Bristol - Ste B
Newport Beach, CA 92660
(714) 851-5010

I HEREBY CERTIFY THAT THIS CORRESPONDENCE
IS BEING DEPOSITED WITH THE U. S. POSTAL
SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE
ADDRESSED TO: COMMISSIONER OF PATENTS AND
TRADEMARKS, WASHINGTON, D. C. 20231, ON

5/15/95
(DATE SIGNED)

May 15, 1995

WALTER A. HACKLER
REG. NO. 27,792

THIS MATERIAL MAY BE
PROTECTED BY COPYRIGHT
LAW (17 USC)

1990

REF
Q11
738
AA1
P536
1990
c.1

USP XXII NF XVII

THE UNITED STATES PHARMACOPEIA THE NATIONAL FORMULARY

*By authority of the United States Pharmacopeial
Convention, Inc., meeting at Washington, D.C.,
March 22-24, 1985. Prepared by the Committee of
Revision and published by the Board of Trustees*

Official from January 1, 1990

ALLERGAN LIBRARY



UNITED STATES PHARMACOPEIAL CONVENTION, INC.
12601 Twinbrook Parkway, Rockville, MD 20852

Other requirements—It meets the requirements for *Identification*, *Loss on drying*, *Heavy metals*, and *Assay for carboxylic acid content* under Carbomer 934P.

Carbomer 941

» Carbomer 941 is a high molecular weight polymer of acrylic acid cross-linked with allyl ethers of pentaerythritol. Carbomer 941, previously dried in vacuum at 80° for 1 hour, contains not less than 56.0 percent and not more than 68.0 percent of carboxylic acid (—COOH) groups. The viscosity of a neutralized 0.5 percent aqueous dispersion of Carbomer 941 is between 4,000 and 11,000 centipoises.

Packaging and storage—Preserve in tight containers.

Labeling—Label it to indicate that it is not intended for internal use.

Reference standard—USP Carbomer Homopolymer Reference Standard.

Viscosity—Proceed as directed in the test for *Viscosity* under Carbomer 934P, except to use a spindle having a disk 2.08 cm in diameter and 0.16 cm high attached to a shaft 0.32 cm in diameter, the distance from the top of the disk to the lower tip of the shaft being 2.7 cm, and the immersion depth being 3.73 cm (No. 5 spindle). The viscosity is between 4,000 and 11,000 centipoises.

Benzene—Proceed as directed in the test for *Benzene* under Carbomer 934P except dilute the *Test preparation* with *p*-xylene to one-fiftieth of its concentration before use. The limit is 0.5%.

Other requirements—It meets the requirements for *Identification*, *Loss on drying*, *Heavy metals*, and *Assay for carboxylic acid content* under Carbomer 934P.

Carbomer 1342

» Carbomer 1342 is a high molecular weight copolymer of acrylic acid and a long chain alkyl methacrylate cross-linked with allyl ethers of pentaerythritol. Carbomer 1342, previously dried in vacuum at 80° for 1 hour, contains not less than 52.0 percent and not more than 62.0 percent of carboxylic acid (—COOH) groups. The viscosity of a neutralized 1.0 percent aqueous dispersion of Carbomer 1342 is between 9,500 and 26,500 centipoises.

Packaging and storage—Preserve in tight containers.

Labeling—Label it to indicate that it is not intended for internal use.

Reference standard—USP Carbomer Copolymer Reference Standard.

Identification—The infrared absorption spectrum of a potassium bromide dispersion of it exhibits maxima only at the same wavelengths as that of a similar preparation of USP Carbomer Copolymer RS.

Viscosity—Proceed as directed in the test for *Viscosity* under Carbomer 934P except to perform the test on a 1.0 percent aqueous dispersion (prepared by using 5.00 g instead of 2.50 g) and omit the 30-minute incubation of the solution before the titration. The viscosity is between 9,500 and 26,500 centipoises.

Carboxylic acid content—Proceed as directed in the *Assay for carboxylic acid content* under Carbomer 934P.

Benzene—Proceed as directed in the test for *Benzene* under Carbomer 934P, except dilute the *Test preparation* with *p*-xylene to one-twentieth of its concentration before use. The limit is 0.2%.

Other requirements—It meets the requirements for *Loss on drying* and *Heavy metals* under Carbomer 934P.

Carbon Dioxide—see Carbon Dioxide USP

Carbon Tetrachloride



CCl₄ 153.82

Methane, tetrachloro-

Carbon tetrachloride [56-23-5].

» Carbon Tetrachloride contains not less than 99.0 percent and not more than 100.5 percent of CCl₄.

Caution—Avoid contact; vapor and liquid are poisonous. Care should be taken not to vaporize Carbon Tetrachloride in the presence of a flame because of the production of harmful gases (mainly phosgene).

Packaging and storage—Preserve in tight, light-resistant containers, at a temperature not exceeding 30°.

Specific gravity (841): between 1.588 and 1.590, indicating between 99.0% and 100.5% of CCl₄.

Distilling range, Method I (721): between 76.0° and 78.0°, a correction factor of 0.043° per mm being applied as necessary.

Acidity—Shake 15 mL with 25 mL of oxygen-free and carbon dioxide-free water for 5 minutes, and allow the layers to separate completely: a 5-mL portion of the aqueous layer is neutral to litmus. Retain the remainder of the aqueous layer for the *Chloride and free chlorine* test.

Nonvolatile residue—Evaporate 50 mL in a platinum or porcelain dish on a steam bath until the volume is reduced to about 1 mL, and allow it to evaporate spontaneously to dryness. Dry at 105° for 1 hour, and weigh: the weight of the residue does not exceed 1 mg (0.002%).

Chloride and free chlorine—A 10-mL portion of the aqueous layer retained from the *Acidity* test exhibits no opalescence upon the addition of a few drops of silver nitrate TS (*chloride*), and a 10-mL portion of the same aqueous solution is not colored blue upon the addition of a few drops of potassium iodide TS and 3 mL of starch TS (*free chlorine*).

Readily carbonizable substances (271)—In a glass-stoppered separator, previously rinsed with sulfuric acid TS, combine 40 mL of it and 5 mL of sulfuric acid TS, and shake vigorously for 5 minutes. Allow the layers to separate completely: the acid has no more color than Matching Fluid A.

Carbon disulfide—Mix 10 mL of it with 10 mL of alcohol potassium hydroxide solution (1 in 10), allow the mixture to stand for 1 hour, then add 5 mL of 6 N acetic acid followed by 1 mL of cupric sulfate TS: no yellow precipitate is formed within 2 hours.

Carboxymethylcellulose Calcium

Cellulose, carboxymethyl ether, calcium salt.

Cellulose carboxymethyl ether calcium salt [9050-04-8].

» Carboxymethylcellulose Calcium is the calcium salt of a polycarboxymethyl ether of cellulose.

Packaging and storage—Preserve in tight containers.

Identification—

A: Shake thoroughly 0.1 g with 10 mL of water, followed by 2 mL of 1 N sodium hydroxide, allow to stand for 10 minutes, and use 1 mL of this solution as the test solution, retaining the